REMARKS

The above-identified Application has been carefully reviewed with the Office Action of April 12, 2011, the Examiner's comments, and the prior art references cited therein in mind. In response thereto, Applicants submit the foregoing amendments and the following arguments in support of patentability. Favorable reconsideration is hereby respectfully requested.

The Applicants election of Group IV in the reply filed January 19, 2010 has been acknowledged in the Office Action. The requirement has been deemed proper by the Office and has therefore been made final. While the Applicants acknowledge this election and the requirement being deemed proper, the Applicants reserve the right to present additional claims at a later date.

Claims 25-28 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Gau et al (U.S. Patent No. 5,084,061).

While the Applicants disagree with this rejection, claims 25-28 have been withdrawn in the instance response; therefore, this rejection has been rendered moot.

Claims 29 and 30 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Gau et al in view of Thome et al (U.S. Patent No. 5,800,486). The Office opines that Gau et al disclose making an intragastric balloon from silicone rubber cast on a mandrel (col. 4, lines 6-7) but do not disclose the method of fabricating an intragastric balloon comprising injecting an elastomer material into a mold in order to obtain a flexible pouch that is to form the envelope of the balloon. The Office uses Thome et al for the disclosure of forming a medical balloon 37 by liquid injection molding from a flexible, medical grade silicone (col. 6, lines 49-51). From these teachings, the Office opines that it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the injection molding process of Thome et al with the intragastric balloon of Gau et al in order to better control the thickness of the resulting intragastric balloon.

Regarding claim 30, the Office opines that Gau et al and Thome et al disclose the invention essentially as claimed except for the mold comprising a top cavity pressed against the bottom cavity with a spherical core positioned between the top and bottom cavity. The Office arrives at the conclusion that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a mold comprising a top cavity pressed against the bottom cavity with a spherical core positioned between the top and bottom cavity in order to create a balloon with a wall thickness and internal hollow volume. This rejection is respectfully traversed.

The Office maintains that the Applicants' arguments filed December 20, 2011 (presumably 2010) have been fully considered but they are not persuasive. The Examiner takes the position that it would have been obvious one having ordinary skill in the art at the time the invention was made to make the dimensional tolerance on the nominal thickens of the balloon envelope in the range of 1-20% since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimal or workable ranges involves only the routine skill in the art. *In re Aller*, 105 USPQ 223. In addition, the Office opines that a change in size or thickness is generally recognized as being within the level of ordinary skill in the art as stated in the case of *In re Rose* 105 USPQ 237 (CCPA 1955). Thus, the Applicants remarks have been summarily dismissed and the grounds of rejection under 35 U.S.C. §103(a) as being unpatentable over Gau et al in view of Thome et al have been maintained for the same reasons as set forth in the previous Office Action. The Applicants respectfully disagree with the position taken by the Office as it appears that the rejection has been maintained using art that is completely non-analogous to the problem addressed by the Applicants.

A prima facie case of obviousness is established only when the prior art teaches or suggests all of the elements of the claims. MPEP § 2143.03, In re Rijckaert, 9 F.3d 1531, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). In addition, "rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning

with some rational underpinning to support the legal conclusion of obviousness." KSR Int'l Co. v. Teleflex, Inc., 127 S. Ct. 1727, 1741, 82 U.S.P.Q.2d 1385, 1396 (quoting In re Kahn, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006)). Applicant respectfully requests that the rejections of claims 29 and 30 be withdrawn for at least the following reasons.

Independent claim 29, as amended, recites:

> A method of fabricating an intra-gastric balloon (1) for treating obesity, said balloon (1) designed to be implanted in the stomach of a patient in order to reduce the volume of the stomach, **said balloon (1) comprising a flexible envelope (2) defining a predetermined inside volume, said flexible envelope (2) being made of an elastomer material, wherein the dimensional tolerance (T) on the nominal thickness (e_{nom}) of the envelope lies in the range of 1% to 20%,** the method comprising:
> injecting an elastomer material into a mold in order to obtain a flexible pouch that is to form **the flexible** envelope (2) on the balloon (1).

As mentioned hereinabove, the Examiner recites that Gau et al disclose an intragastric balloon except for the dimensional tolerance being in the range of 1-20% or 10-16%. (Emphasis added) Gau et al further recite that their balloon will have a final thickness of approximately 0.006 to 0.25 inches. Such a variation is considerably different from the balloon produced by the Applicants as the dimensional tolerance on the nominal thickens of the envelope lies in the range of 1% to 20%. Thus, it is unquestioned that the intragastric balloon of Gau et al can result in the shell having extremely wide variations in thickness throughout the structure. This fact has been admitted by the Office in a previous rejection where the balloons produced by this method provide insufficient dimensional accuracy which can lead to certain zones of the balloon being too thick, thereby increasing the cost of producing the balloon, or to create other zones of the balloon not being thick enough, which can lead to the balloon being fragile. This is not acceptable for an intragastric balloon.

Thome et al deal with transurethral thermal therapy with a cooling balloon. Thus, it is further unquestioned that not only is the field of endeavor completely non-analogous to the field of the Applicants, but it does not disclose the dimensional tolerance of the elastomeric shell as

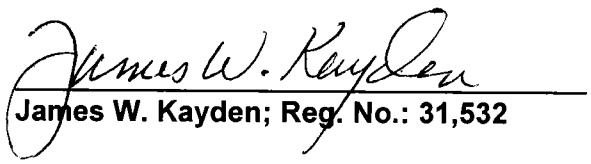
claimed in the present application. Thome et al disclose forming a medical balloon by liquid injection molding from flexible, medical grade silicone, however, they never disclose the dimensional tolerance of the elastomeric shell. One of ordinary skill in the art at the time the invention was made would not have the information concerning the effects of the liquid injection molding forming method on the dimensional tolerance of the elastomeric shell and thus would have no motivation or teaching to combine the two references. Furthermore, since Thome et al deals with small balloons used with a catheter, the balloons have a huge difference in size compared with intragastric balloons which would discourage one of ordinary skill in the art at the time the invention was made to apply this forming method to an intragastric balloon.

The only teaching of a method of fabricating an intragastric balloon for treating obesity, having a defined inside volume, with a dimensional tolerance on the nominal thickness of the envelope lying in the range of 1% to 20%, comes from the Applicants' own disclosure. Thome et al only teach that the tip portion 38 and the retension balloon 37 of tip 34 are formed by liquid injection molding. The combined teachings, therefore, do not teach or even fairly suggest the inventive method taught by the Applicants' claims 29 and 30.

CONCLUSION

With the amendments presented herein, it is believed that all the claims remaining in the Application are in condition for allowance. Early and favorable action in this regard is hereby respectfully requested. Should there be any minor informalities remaining, the Examiner is respectfully requested to call the undersigned attorney so that this case may be passed to issue at an early date.

Respectfully submitted,



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